



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,124	03/31/2006	Dominique M. Freeman	PEL-2784	4918
77845	7590	06/17/2011		
Goodwin Procter LLP Attn: Patent Administrator 135 Commonwealth Drive Menlo Park, CA 94025-1105			EXAMINER EDWARDS, LYDIA E	
			ART UNIT 1775	PAPER NUMBER
			NOTIFICATION DATE 06/17/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patentsv@goodwinprocter.com
dnakley@goodwinprocter.com

Office Action Summary	Application No. 10/541,124	Applicant(s) FREEMAN ET AL.	
	Examiner LYDIA EDWARDS	Art Unit 1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-23,28,29 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40 is/are allowed.
- 6) ☒ Claim(s) 1,6-8,17-23,28,29 and 34-39 is/are rejected.
- 7) ☒ Claim(s) 9-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/5/2011 and 6/1/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/25/2011 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1, 6-23, 28-29 and 34-40 have been considered but are moot in view of the new ground(s) of rejection.

The indicated allowability of claims 28, 29 and 34-39 are withdrawn in view of the newly discovered reference(s) to Wolfbeis et al.. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 contains the trademark/trade name TERGITOL TMN. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the emulsifiers and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 28 is rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al. (US 6,576,101).

Regarding Claim 28, Heller ('101) discloses collecting a sample of 500 nL or less (Col 5, lines 50-67), and covering an electrochemical sensor with the sample for determining an analyte concentration using a potentiometric technique (Col 1 line 59- Col 2 line 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. (U.S. 6036924) in view of Lum et al. (GB 2335990) in view of Betts et al. (US 5405510) further in view of Wolfbeis et al. (*Sol-gel based glucose biosensors employing optical oxygen transducers, and a method for compensating for variable oxygen background*, Biosensors & Bioelectronics 15 (2000) pages 69-76).

Regarding Claims 1, and 6-7 and, Simons et al. ('924) discloses a cartridge (246) having a plurality of analyte detecting members (210) mounted on said cartridge, the cartridge comprising cavities (wells, 44), a plurality of penetrating members (216 connected to 224) which are contained at least partially in the cavities and are slidably movable to extend outward from the openings on the cartridge (col. 5 lines 16-26). Simons et al. also discloses a plurality of chambers each associated with a cavity that are positioned along an outer periphery of the cartridge. An analyte detecting member is associated with each chamber and forms a portion of one wall of the plurality of chambers (Fig. 3A, 220 and col. 8 lines 19-29). Simons et al. discloses that the test area can be the absorbent material 218 or the surface beneath it which is a wall of the chamber. Simons et al. discloses the invention as stated above regarding claim 1 and further discloses that the chamber is positioned substantially adjacent an outer periphery of the cartridge (Fig. 6D) and at least one opening in one of the chambers which leads fluid along a fluid path toward an analyte detecting member (col. 8 lines 19-22 and lines 29-35 and col. 7 lines 40-49).

Simons fails to disclose a position sensor coupled to the plurality of penetrating members, the position sensor utilizing position information of a penetrating member to determine a depth of penetration through a skin surface.

Lum et al. ('990) discloses that it is old and well known in the art to use a position sensor coupled to a penetrating member, the position sensor utilizing the position information of the penetrating member to determine the depth of penetration through the skin. In particular, Lum et al. discloses a penetrating member that uses a sensor that senses the different impedance values of the different layers of skin to determine information on which layer of skin the penetrating member is positioned within (p. 3, lines 4-7). Lum et al. further discloses that this information helps to minimize the trauma and pain of over-penetration as well as avoid the frustration and pain of unsuccessful blood sampling because of inadequate penetration (p. 3, lines 16-23). Lum et al. discloses that these advantages are especially pertinent to patients such as diabetics, who have to sample blood often (p. 1, lines 22-23). Simons et al. disclose that the cartridge of their body fluid sampling device may be used in conjunction with a glucometer (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Simons et al. to include a position sensor coupled to the plurality of penetrating

members, the position sensor utilizing position information of a penetrating member to determine a depth of penetration through a skin surface as made obvious by Lum et al. in order to avoid the problems associated with over-penetration or inadequate penetration.

Simons fails to disclose a memory on said device.

Betts et al. ('510) discloses memory on a analyte measuring system for fluid samples (Col 5, lines 16-65 and Col 6, line 34-59)

It would have been obvious to one of ordinary skill in the art to modify the device of Simons et al. and Lum et al. with a memory on the device as taught by Betts et al. to employ a means for calibration and analysis of the samples.

Simons also fails to disclose wherein the analyte detecting member comprises an emulsion of Ru sensing phase within a group of oxidase sensing members.

Wolfbeis et al. teaches a sol-gel based glucose biosensor comprising an emulsion of Ru sensing phase within a group of oxidase sensing members (See Abstract and Pages 70-71).

It would have been obvious to one of ordinary skill in the art to modify the device of Simons et al., Lum et al. and Betts et al. with a Ru sensing phase within a group of oxidase sensing members as taught by Wolfbeis et al. as a means to improve enzyme activity, response time and operational as well as storage life time.

Regarding Claim 8, the examiner interprets the hydrophile-lipophile balance (HLB) to be a property/characteristic of the emulsion as described in claim 1; furthermore, the examiner views the properties and/or characteristics of the of the emulsion to be an inherent property.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. (U.S. 6036924) in view of Lum et al. (GB 2335990) in view of Betts et al. (US 5405510) further in view of Wolfbeis et al. (*Sol-gel based glucose biosensors employing optical oxygen transducers, and a method for compensating for variable oxygen background*, Biosensors & Bioelectronics 15 (2000) pages 69-76) as disclosed above in claim 1, further in view of Gough (US 2002/0156355).

Regarding Claim 17, the combination of Simons et al., Lum et al., Betts et al. and Wolfbeis et al. discloses the device of claim 1 except for analyte members having differing sensitivity ranges.

Gough ('355) discloses analyte members having differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample and a hydrophilic membrane coating the sensor (paragraph 44).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Simons et al., Lum et al., Betts et al. and Wolfbeis et al. to include analyte members have differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample and a hydrophilic membrane coating the sensor as taught by Gough in order to optimize the systems sensor response.

Claims 18 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. (U.S. 6036924) in view of Lum et al. (GB 2335990) in view of Betts et al. (US 5405510) further in view of Wolfbeis et al. (*Sol-gel based glucose biosensors employing optical oxygen transducers, and a method for compensating for variable oxygen background*, Biosensors & Bioelectronics 15 (2000) pages 69-76) as disclosed above in claim 1, further in view of Aceti et al. (US 2002/0087056).

Regarding Claim 18, the combination of Simons et al., Lum et al., Betts et al. and Wolfbeis et al. discloses the device of claim 1 except disclosing a specific volume.

Aceti ('056) discloses a system where 300nL are used (paragraph 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Simons et al., Lum et al., Betts et al. and Wolfbeis et al. to include only using 300nL sample in order to create a compact system with small sample chambers for analysis.

Regarding Claims 20-23, the combination of Simons et al., Lum et al., Betts et al. and Wolfbeis et al. discloses the device of claim 1 except for the volume of the detecting members.

Aceti discloses a system where more than 160 sample chambers are used (paragraph 36, the examiner notes that in the combination the density would be higher than 4.53/50 since 160 or more sample chambers would be used).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Simons et al., Lum et al., Betts et al. and Wolfbeis et al. to include having 160 or more sample chambers as taught by Aceti in order to provide a longer lasting system for use.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. (U.S. 6036924) in view of Lum et al. (GB 2335990) in view of Betts et al. (US 5405510) further in view of Wolfbeis et al. (*Sol-gel based glucose biosensors employing optical oxygen transducers, and a method for compensating for variable oxygen background*, Biosensors & Bioelectronics 15 (2000) pages 69-76) as disclosed above in claim 1, further in view of Moreman et al. (US 6706159).

Regarding Claim 19, the combination of Simons et al., Lum et al., Betts et al. and Wolfbeis et al. discloses the device of claim 1 except for a mesh configured fluid spreader positioned over said analyte detecting member.

Moerman ('159) discloses a mesh positioned over the detection members (mesh strips 94, the examiner notes that this mesh can be configured to spread fluid over the detection member even though there is no specific disclosure to its function).

It would have been obvious to one of ordinary skill in the art to modify the device of Simons et al., Lum et al. and Betts et al. in order to optimize the sensor response of the amount of target analyte detected.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (U.S. 6977722) in view of Dujardin (US 2880876).

Regarding Claim 29, Wohlstadter et al. ('722) teaches an assay module (e.g. cartridges) wherein the assay module has a plurality of assay domains or assay regions and, preferably, one

or more wells or chambers (Col 9, line 65-Col 10, line 9); wherein the assay modules can be used to test a variety of samples which may contain an analyte or activity of interest. Such samples may be in solid, emulsions (Col 103, lines 24-26); and also where assay domains may be formed by depositing reagents on the surface. (Col 23, line 52-Col 24, line 36).

However, he does not teach a process of scraping away emulsion from the tops of the wells.

Dujardin ('876) teaches a process for scraping away emulsion from the top of a reservoir (Col 2, lines 17-36, 50-65).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wohlstadter et al. with the process of removing unwanted emulsion as taught by Dujardin in order to remove any unwanted portion of the emulsion.

Claims 34-35 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreman et al. (US 6706159) in view of Perez et al. (US 6866675) in light of Stewart et al. (US 6447119).

Regarding Claims 34-35, 37-39, Moerman discloses a cartridge with a plurality of cavities (Col 7, line 56 to Col 8, line 18, where the cavities are formed by the stacking of elements 84, 85, and 86), an electric penetrating driver (Col 7, lines 15-25 and Col 8, lines 19-43, the examiner notes that if the system is automated there must be an electrical actuator for rotating cam ring 86 to drive the penetrating members), A plurality of penetrating members housed in the cavities and individually moveable by said driver (see figure 8G, Col 8, lines 19-43), a plurality of analyte detecting members defining an array (elements 814) where each cavity has one analyte array (see figures 8C-F). Moreman et al. also discloses a memory device, for example EEPROM, in which information including calibration information and previous results may be stored (Col 9, lines 47-50). Moreman et al. fails to disclose an optical assembly and an optical detector.

Perez et al. ('675) teaches wherein a sufficient amount of body fluid has been drawn into annular space [530], apparatus [500] is placed into analysis equipment, such as blood glucose measuring device [580] shown in FIG. 5B. The analysis equipment may use optical transmittance, reflectance, fluorescence or direct sampling with electrical and/or chemical stimuli

to test the fluid sample in conventional fashion (Col 10, lines 58-67). Perez et al. is silent towards the components within the analysis equipment however, the examiner takes the position that it is an inherent property of the analysis equipment of Perez to include an optical assembly and an optical detector, and a diffuser, in order to provide optical transmittance, reflectance, fluorescence testing of the fluid sampling.

Perez et al. ('675) is silent with the regards to an optical assembly and an optical detector, and a diffuser, therefor it would have been necessary and thus obvious to look to prior art for conventionally an optical assembly and an optical detector, and a diffuser. Stewart et al. ('119) provides this conventional teaching showing (See Col 4, lines 18-32) that it is known in the art at the time the invention was made to modify the device of Moreman et al. and Perez et al. to include an optical assembly and an optical detector, and a diffuser, motivated by the expectation of successfully practicing the invention of Moreman et al. and Perez et al. in order to provide optical transmittance, reflectance, and fluorescence testing of the fluid sampling.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moreman et al. (US 6706159) in view of Perez et al. (US 6866675) in light of Roustaei (US 6729546).

Regarding Claim 36, Moerman discloses a cartridge with a plurality of cavities (Col 7, line 56 to Col 8, line 18, where the cavities are formed by the stacking of elements 84, 85, and 86), an electric penetrating driver (Col 7, lines 15-25 and Col 8, lines 19-43, the examiner notes that if the system is automated there must be an electrical actuator for rotating cam ring 86 to drive the penetrating members), A plurality of penetrating members housed in the cavities and individually moveable by said driver (see figure 8G, Col 8, lines 19-43), a plurality of analyte detecting members defining an array (elements 814) where each cavity has one analyte array (see figures 8C-F). Moreman et al. also discloses a memory device, for example EEPROM, in which information including calibration information and previous results may be stored (Col 9, lines 47-50). Moreman et al. fails to disclose an optical assembly and an optical detector.

Perez et al. ('675) teaches wherein a sufficient amount of body fluid has been drawn into annular space [530], apparatus [500] is placed into analysis equipment, such as blood glucose measuring device [580] shown in FIG. 5B. The analysis equipment may use optical

Art Unit: 1775

transmittance, reflectance, fluorescence or direct sampling with electrical and/or chemical stimuli to test the fluid sample in conventional fashion (Col 10, lines 58-67). Perez et al. is silent towards the components within the analysis equipment however, the examiner takes the position that it is an inherent property of the analysis equipment of Perez to include an optical assembly and an optical detector, and a grating.

Perez et al. ('675) is silent with the regards to an optical assembly and an optical detector, and a grating, therefor it would have been necessary and thus obvious to look to prior art for conventionally an optical assembly and an optical detector, and a grating. Roustaei ('546) provides this conventional teaching showing (See Abstract and Col 3, lines 59-64) that it is known in the art at the time the invention was made to modify the device of Moreman et al. and Perez et al. to include an optical assembly and an optical detector, and a grating, motivated by the expectation of successfully practicing the invention of Moreman et al. and Perez et al. in order to provide optical transmittance, reflectance, and fluorescence testing of the fluid sampling.

Allowable Subject Matter

Claim 40 is allowed.

Regarding Claim 40 the prior art fails to disclose a slurry laid over a well of the anatyte detecting member; a plurality of luminescent beads of the same color with different non-overlapping lifetimes ranges for their particular anatyte, said beads in said slurry.

Claims 9-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on 571.272.1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael A Marcheschi/
Supervisory Patent Examiner, Art Unit 1775

/LYDIA EDWARDS/
Examiner
Art Unit 1775

LE